K012785

8.0 PREMARKET NOTIFICATION 510(K) SUMMARY

NOV 1 6 2001

Applicant: HealthTronics, Inc.
1841 West Oak Parkway
Marietta, Georgia 30062
Telephone: 770-419-0691
Facsimile: 77-419-9490

Manufacturer: HMT High Medical Technologies, AG
Lengwil, Switzerland

Official Correspondent: Peter Weiman
Manager, Clinical Programs
HealthTronics, Inc.

The TwinTrode® ELC 134 Electrode is a multiple patient use electrode for electrohydraulic extracorporeal shock wave lithotripter. It is substantially equivalent to the NewTrode® ELC 124 Electrode (predicate device). Both electrodes are components of the HealthTronics LithoTron Lithotripsy System.

The TwinTrode and NewTrode devices are very similar and are utilized as part of the LithoTron system identically. The TwinTrode differs from the NewTrode in that the longevity of the TwinTrode is up to 2.5 times greater than the longevity of the NewTrode. Performance testing verifying this increase in total useable shocks has been provided in the 510(k). Clinical data were not required to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2001

Mr. Peter Weiman
Manager of Clinical Programs
HealthTronics Surgical Services, Inc.
1841 West Oak Parkway, Suite A
MARIETTA GA 30062-9923

Re: K012785
Trade/Device Name: Twin Trode® ELC 134 Electrode
Regulatory Number: 21 CFR 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: August 15, 2001
Received: August 20, 2001

Dear Mr. Weiman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

NOV 1 6 2001

510(k) Number (if known): K012785

Device Name: TwinTrode® ELC 134 Electrode

Indications for Use:

The TwinTrode® ELC 134 Electrode, is intended for multiple patient use during lithotripsy procedures as a replacement electrode to be used with the LithoTron Lithotripsy System.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012785

Prescription Use ✓